REMARKS

Claims 2-6 are canceled. Claims 11-50 are withdrawn from consideration. Claims 1 and 7 have been amended and new claims 51-56 have been added. The new and amended claims are supported throughout the application, e.g., at page 7, lines 11-18; page 81, lines 3-21; page 49, line 11 to page 50, line 12; and page 51, line 6 to page 53, line 22. No new matter has been added. Upon entry of the present amendment, claims 1 and 7-56 are pending and claims 1, 7-10 and 51-56 are under exam.

Rejections Under 35 U.S.C. §112

The Examiner has rejected claims 1-10 under 35 U.S.C. § 112, first paragraph, based on "failure of the instant disclosure to provide adequate written description of an Ikaros transcriptional control region" and on the specification being "silent with respect to any specific sequence regarded as an Ikaros transcriptional control region" (Office Action, pages 4 and 5). In support of the rejection, the Examiner asserts that:

> the specification is silent with respect to what would be defined as transcriptional control region. . . .no specific functional attributes [are] described in the specification which would be considered indicative of an Ikaros regulatory element. Further, there is no specific definition of a control region being active or inactive in any particular context which clearly defines an assay to test whether a specific sequence is a or [*sic*] part of a Ikaros transcriptional control region" (Office Action at page 5).

This rejection has been overcome by the present amendments to the claims.

Claim 1 has been amended to specifically define the Ikaros regulatory elements. As amended, the regulatory regions covered by the claims are defined by their presence in specifically sized fragments of lymphoid-specific DNaseI HSS of the Ikaros locus. New claims have been added that recite an isolated DNA comprising an Ikaros gene sequence that is amplifiable from genomic DNA using specific primers (SEQ ID NO:29 and SEQ ID NO:30). These limitations define explicit physical and chemical characteristics of the claimed molecules

sufficient to satisfy the written description requirement. In its Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirement, the PTO states:

> [f]actors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the method of making the claimed invention (66 Fed. Reg. 1099 (Jan. 5, 2001), emphasis added).

The present claims satisfy this standard as they provide "structure, physical and/or chemical properties" of the claimed molecules. In addition, the claims are limited by function in that they require transcriptional regulatory activity. This activity is readily assayable using techniques known in the art and provided in the specification. Indeed, the specification is replete with examples and discussion of Ikaros transcriptional control regions that fall within the claims, and their use. For example, Applicant draws the Examiner's attention to the transgenic animal experiments described in the specification involving constructs of Ikaros regulatory elements using, e.g., the β and γ clusters. The specification describes transgenic mice expressing constructs referred to as R19-GFP and R10-GFP (at page 81, line 11 to page 83, line 31) which include sequences that fall within claims 1 and 51. In particular, the expressed constructs include either the β or γ cluster (recited in claim 1) cloned upstream of a reporter molecule. The activity of R19 and R10 was tested and it was found that these are <u>active</u> Ikaros promoter regions (see page 83, lines 27-31), and not merely "putative promoters" (as the Examiner states at page 6 of the Office Action). In particular, the specification states that "the activity and tissue specificity of these promoter regions was examined by following their <u>ability to drive expression</u> of a GFP reporter in a variety of blood cells" (at page 82, lines 8-9). Further, the specification states that "[w]hereas the activity of R19 is restricted to neutrophils, R10 is active in B cells and in a smaller fraction of neutrophils" (at page 83, lines 28-29). Contrary to the Examiner's comment, one skilled in the art would recognize that the disclosed <u>ability to drive expression</u> is a specific and readily assayable functional attribute of an Ikaros regulatory element. These

experiments also show that Applicant was clearly in possession of the invention, since the constructs and transgenic mice were made and are described in detail in the specification.

The Examiner also argues that the claims "are broad, encompassing an enormous number of species of Ikaros transcriptional control region from any species of organism" (Office Action at page 5). This basis for the rejection has been overcome by amending the claims to be limited to sequences from mouse or human.

The Examiner also asserts that the specification does not disclose transcription factors implicated in the control of the Ikaros transcriptional control region. Applicants note that the present invention is not drawn to transcription factors involved in the regulation of Ikaros. Rather, the claims cover Ikaros genetic sequences. Applicant has sufficiently defined the claimed seqeunces by structural and functional characteristics. Knowledge of the specific transcription factors that may bind to the sequence recited in the claims is not necessary to describe, nor to make and use, the claimed molecules. Thus, this part of the Examiner's argument does not support a §112 rejection of the present claims.

In view of the foregoing, Applicant requests that the rejection be withdrawn.

Enclosed is a Petition for Extension of Time along with the required fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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